

## FLUID-TIGHT DILUTION BOTTLE AND CAP

## BACKGROUND OF THE INVENTION

5       The use of buffered and microbiological growth media for microbiological assays is widespread. To obtain accurate assays, it is important that the volume of the fluid be exact to obtain proper dilution of, for example, a bacteria-containing sample, and of paramount 10 importance that its sterility is ensured. It is also important that the concentration of the buffer or growth media components have a predetermined known value. This may be achieved by the preparation of fresh batches of the assay fluids, measuring and/or adjusting the 15 concentration of the components, then using the assay fluids promptly thereafter. The chief drawback of this approach is that it is both time-consuming, labor-intensive and subjects the assay fluid to the possible introduction of sterility-destroying microorganisms.

20      An alternative, simpler approach has been to use premade sterile microbiological assay fluids that come in specific volumes and concentrations. However, in order to maintain sterility and the proper volume and concentration during storage and shipping, such premade 25 fluids must be contained in fluid-tight containers that prevent the entry of microorganisms and that permit essentially no loss of fluid either through leakage or evaporation. This may be achieved by the use of a container having, for example, a molded breakable seal 30 formed essentially integrally with the container's opening. The drawback of such an approach is that, once the seal is broken, the fluid must be used immediately and any remainder discarded.

35      The achievement of absolutely fluid-tight reusable containers has been difficult, with even the most fluid-tight containers exhibiting leakage when they are shipped by air, where the lower atmospheric pressure

existing at high altitudes, coupled with a lowered vapor pressure of the fluid combine to create a higher relative pressure inside the container, thereby tending to force the liquid out of the container.

5 There is therefore a need in the art for a fluid-tight container that exhibits essentially no loss of fluid during storage and shipping, including shipment by air, that remains sterile until it is used and that, once opened, may again be sealed to maintain sterility  
10 and the predetermined volume and concentration of the assay fluid's components, and which permits retesting of the assay fluid in a simple and convenient manner.

15 The foregoing need is met by the present invention, which is summarized and described in detail below.

#### BRIEF SUMMARY OF THE INVENTION

The invention consists of a cylindrical vial and a cap that fits over the opening of the vial, the  
20 vial and cap being provided with various features aimed at creating a fluid-tight seal even at the high altitudes encountered during shipment by airplane, and that may be broken by the user when access to the vial's contents is desired and that, once opened, may be resealed to  
25 preserve sterility. The top of the vial is provided with a lip, screw threads below the lip and a ratchet-toothed ring below the screw threads, with all three of these features preferably being integrally molded with the top of the vial. The inside of the cap is provided with  
30 screw threads to mate with the screw threads of the top of the vial and a ratchet-toothed ring that engages the ratchet teeth of the corresponding ratchet-toothed ring of the top of the vial. In addition, the cap is provided with a frangible peel-away strip that permits a hinged  
35 flip-top lid to be freed for opening and closing the vial cap. Finally, the flip-top of the cap is provided with an inner flange that engages the top lip of the vial

after removal of the peel-away strip for a secure compression fit, with the flange having a tongue portion in the area of the hinge that guides the flip-top into the correct position for closure.

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#### BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

FIG. 1 is an exploded perspective view of the container and cap combination of the invention.

10 FIG. 2 is a perspective view of the opposite side of the cap portion shown in FIG. 1, featuring a frangible peel-away strip and pull tab.

FIG. 3 is a side view of the container portion of the invention.

15 FIG. 4 is a top view of the cap portion of the invention.

FIG. 5 is a side view of the cap portion of the invention.

FIG. 6 is a view of the inside of the cap portion of the invention as viewed from the bottom.

20 FIG. 7 is a sectional view of the cap shown in FIG. 4 taken along the plane 7-7.

FIG. 8 is a sectional view of the cap shown in FIG. 4 taken along the plane 8-8.

25 FIG. 9 is a view of the inside of the cap portion of the invention as viewed from one side of the bottom.

FIG. 10 is a view of the inside of the cap portion of the invention as viewed from another side of the bottom.

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#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to the drawings, wherein like numerals refer to the same elements, there is shown the inventive vial comprising container 1 and cap 2 designed 35 for fluid-tight mating with each other. Container 1 comprises an open-ended substantially cylindrical bottle 10 provided with a lip 12, threads 14 and outwardly

projecting ratchet-toothed ring 16, with all three of these features being located proximal to the open end and preferably being integrally molded with the bottle 10.

Both container 1 and cap 2 are preferably 5 molded from polymeric material, more preferably polyethylene and most preferably from recyclable high density polyethylene.

Cap 2 comprises a skirt 22 and flip-top 30 that are integral when frangible strip 27 is in place, but 10 which are in a hinged relationship after the frangible strip 27 is removed by pulling on strip tab 28 to peel away the strip. Flip-top 30 is provided with a flexible hinge 32, pull tab 34, an inner circumferential flange 36 that is adapted to engage lip 12 of the vial after the 15 frangible strip is removed, with flange 36 having a tongue portion 38 that guides flip-top 30 into place so that flange 36 is properly aligned with lip 12.

Skirt 22 is provided on its inner wall with screw threads 24 adapted to engage corresponding screw 20 threads 14 of bottle 10, and with an inwardly projecting ratchet-toothed ring 26 adapted to engage the corresponding outwardly projecting ratchet-toothed ring 16 of bottle 10.

In a typical application the vial is filled 25 with 90 or 99 mL of either an aqueous buffered solution or an aqueous microbiological growth medium comprising, for example, a peptone at a certain concentration. The cap is threaded onto the vial and compressed while twisting so that the corresponding ratchet-toothed rings 30 engage and permanently lock the cap to the vial by a compression fit that is fluid-tight. When ready for use in conducting a microbiological assay to assess the degree of sterility in an environment, the peel-away strip is removed, a 1 mL or 10 mL sample containing, for 35 example, suspected bacteria is injected into the fluid-containing vial to dilute the sample to 1 or 10 vol%, the flip-top is snapped close, the mixture is agitated to

ensure thorough mixing, and the so-diluted sample is allowed to incubate for an appropriate time period. Following incubation, samples of the contents of the dilution vial are deposited on solid growth media in, for 5 example, petri dishes, and colony counts are conducted to identify the nature and degree of bacterial contamination. The remaining contents of the vial may be preserved in a sterile condition for possible later assays to specifically identify a possible pathogen by 10 simply closing the vial's flip-top and storing the vial in an appropriately refrigerated environment.

Leakage testing of fluid-filled vials of the invention was conducted both by actual air transport at commonly encountered commercial air shipment altitudes of 15 up to 10,000 feet and in a vacuum chamber under reduced pressure to simulate the environment encountered in the cargo hold of an airplane at altitudes of up to 12,000 feet. There was no loss of fluid with either type of test.

20 The terms and expressions which have been employed in the foregoing specification are used therein as terms of description and not of limitation, and there is no intention, in the use of such terms and expressions, of excluding equivalents of the features 25 shown and described or portions thereof, it being recognized that the scope of the invention is defined and limited only by the claims which follow.